K082031

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

The information contained in this premarket notification 510(k) summary is submitted as required by 21 CFR 807.92:

1. Type of Submission

510k Traditional submission for New Devices

JUL 31 2008

2. Applicant Company:

APPASAMY ASSOCIATES,
20, SBI Officers Colony, 1st Street,
Arumbakkam, Chennai – 600 106 INDIA
Ph: 91 (044) 3298 0153
Fax: 91 (044) 2363 0721
www.appasamy.com

3. Applicant (Contact Person) Name:

R.N.Kasthuri
Vice Chairman

4. Date Summary Prepared:

May 31, 2008

5. Device Trade / Proprietary Name:

Slit Lamp AIA – 11 Series:

Slit Lamp AIA – 11
Slit Lamp AIA – 11 3S
Slit Lamp AIA – 11 5S
Slit Lamp AIA – 11 ZOOM

Slit Lamp AIA – 12 Series:

Slit Lamp AIA – 12
Slit Lamp AIA – 12 3S
Slit Lamp AIA – 12 5S
Slit Lamp AIA – 12 ZOOM

6. Common Name:

Slit Lamp

7. Classification Name:

AC-Powered Slit Lamp Bio microscope

8. Class:

II

9. Classification Panel:

86

10. Product Code:

HJO

11. Regulation Number:

21CFR 886.1850

12. Device Description:

An AC-powered Slit Lamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects in to the patient's eye through a control diaphragm a thin, intense beam of light. Slit lamp examination is done to look at the front parts of the eye, including the cornea, lens, iris and the front section of the vitreous gel.

Slit Lamp AIA-11 Series (AIA-11, AIA-11 3S, AIA-11 5S, AIA-11 Zoom) have the same operating characteristics and intended use. These models differ only in the number of Magnification.

Slit Lamp AIA-12 Series (AIA-12, AIA-12 3S, AIA-12 5S, AIA-12 Zoom) have the same operating characteristics and intended use. These models differ only in the number of Magnification.

The device and accessories are indicated as a noninvasive aid in the examination and diagnosis of the eye conditions. It is also used to fit the contact lenses.

Device Design:

Slit Lamp construction is divided as five sub Assemblies, which are:

1. Cross slide assembly
2. Illumination (Light Source) Assembly
3. Table Top with Power Supply Assembly
4. Chinrest Assembly
5. Microscope Assembly

13. Intended Use:

Slit Lamp is an AC-powered slit lamp biomicroscope intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior eye segments.

14. Identification of a Legally Marketed Predicate Device:

The following shows the substantially equivalent predicate devices to our submitted new devices

a) Appasamy AIA-11 Series Slit Lamps are substantially Equivalence to the following Predicate device:

I. Company: Naveen Intl, Inc
Model: AIA – 11 Slit Lamp
510(K) No.: K953030

II. Company: CSOS.R.L
Model: SL 990 Slit Lamp
510(K) No.: K992836

III. Company: Woodlyn Inc
Model: Woodlyn HR-1 Slit Lamp
510(K) No.: K900476

b) Appasamy AIA-12 Series Slit Lamps are substantially Equivalence to the following Predicate device:

I. Company: Reichert, Inc
Model: Xcel 255 Slit Lamp
510(K) No.: K063750

15. Summary of Technological Characteristics:

Comparisons of technological characteristics of the Appasamy Slit Lamps with Predicate Devices were performed and found to substantially equivalent.

16. Guidance on the Recognition and Use of Consensus Standards:

Slit Lamp AIA-11 Series and AIA-12 Series are complies with the requirements of listed FDA Recognized Consensus Standards.

a) **ISO 10939:2007,** Ophthalmic instruments — Slit Lamp Microscopes

b) **ISO 15004-2:2007,** Ophthalmic instruments — Fundamental requirements and test methods Part 2: Light hazard protection

c) **IEC 60601-1,** Medical Electrical Equipment - Part 1: General Requirements for Safety

17. Optical equivalency and radiation safety:

Slit Lamp AIA-11 Series and AIA-12 Series are complies with the required optical radiation standards listed in the FDA. (**ISO 15004-2:2007,** Ophthalmic instruments — Fundamental requirements and test methods Part 2: Light hazard protection)

18. Operation method (Prepare the Patient and the Instrument):

a) The instrument is placed in front of the patient and the patient rests his/her chin and forehead on a support to keep their head steady
b) Adjust the chin-rest by rotating the handle so that the patient's eyes are in line with the microscope & illumination centre
c) Switch the instruments ON; the indicator light (Green) is ON, on the power supply.
d) Adjust the luminous intensity by regulate the regulator
e) Focus the eye to be examined by moving the joystick in the Cross Slide
f) Patient's eyes are then examined or diagnosed through the biomicroscope

19. Operation Principles:

a) The instrument is consist of a Cross Slide, a microscope, a illumination system providing a slit image, Chinrest and a power supply
b) AC Power is converted to DC Power through the SMPS
c) DC Power is supplied to the Lamp
d) The slit width is adjusted through the Slit shutters and Aperture.
e) The slit image is illuminate the eye
f) Observe the eye through the microscope

20. How to prepare for the test:

No special preparation is necessary for the test.

21. Usage of the Slit Lamp:

The Slit Lamp test is used to examine the eyelids, the sclera, conjunctiva, iris, lens, and the cornea.

The slit lamp exam may detect many diseases of the eye, including:

- Cataract
- Corneal injury
- Macular degeneration
- Presbyopia
- Retinal detachment
- Retinal vessel occlusion
- Retinitis pigmentosa
- Steve Johnson syndrome
- uveitis

22. Indication for use:

Slit Lamp AIA-11 Series and AIA-12 Series are intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior eye segment

23. Marketing history:

Our devices, Slit Lamp AIA – 11 Series & AIA – 12 Series have been distributed in the following countries:

Australia,	Georgia,	Russia,
Bangladesh,	Indonesia,	Singapore,
Brazil,	Lebanon,	South Africa
Cameron,	Libya,	Srilanka,
China,	Lithvenia,	Sweden,
Coulombs,	Malaysia	Syria,
Dubai,	Nepal,	Turkey,
Egypt,	Peru,	UAE,
England,	Philippines,	Vietnam,
France,	Poland,	

No special warnings have been issued in connection with the above-mentioned medical device.

Warnings issued are per the product guides under the section "Warnings".

24. Warnings, Photo Toxicity Information and Precautions:

WARNINGS:

- Use only the type of power source that indicated on label.
- Connect the Equipment to properly grounded power outlets.
- Unplug the Equipment before servicing / cleaning it.
- Confirm the AC power cord meets the relevant local safety standards.
- Don't use damaged power cord.
- Only trained personal service / handle the equipment.
- Unplug the Equipment before changing the Fuse.
- Check the electrical connections periodically; any defects noticed, like loose connections, damaged to insulation in the electrical wires etc., should be rectified immediately.
- Be ensuring the table level is parallel to ground.

INTENSITY WARNING (PHOTO TOXICITY INFORMATION)

"Because prolonged intense light exposure can damage retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness

setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400 nm) and, whenever possible filters that eliminate short-wavelength blue light (<420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of the radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for slit lamps, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

PRECAUTIONS:

- Before using the Equipment, read instructions carefully.
- Handle the Equipment carefully.
- Touch the Bulb glass with clean cloth.
- Use proper methods to clean optics and Equipment.
- Before switch off, turnoff regulator.
- Cover the Equipment when not in use.
- Don't touch the Bulb immediately after switch off. It is in hot condition. Allow sufficient time to cool.
- Don't touch the Mirror surface or exposed lenses, and keep them clean.
- Don't rub the Gliding plate.
- Don't move Base on rails while locking knobs at on.
- Don't spill liquid into the Equipment.
- Don't use any hazardous solvents to clean the optics and parts.

25. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, APPASAMY ASSOCIATES concludes that the Slit Lamp AIA – 11 Series & Slit Lamp AIA – 12 Series are safe and effective, and substantially equivalent to predicate devices as described herein.

26. APPASAMY ASSOCIATES will update and include in this summary any other information deemed seasonably necessary by the FDA.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Appasamy Associates
c/o Ned Devine
Underwriters Laboratories Inc.®
333 Pfinsten Rd.
Northbrook, IL 60062

JUL 31 2008

Re: K082031
Trade/Device Name: AC-Powered Slit Lamp Bio Microscope, Models Slit Lamp AIA-11, Slit Lamp AIA-11 3S, Slit Lamp AIA-11 5S, Slit Lamp AIA-11 Zoom, Slit Lamp AIA-12, Slit Lamp AIA-12 3S, Slit Lamp AIA-12 5S, Slit Lamp AIA-12 zoom
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slit Lamp Bio microscope
Regulatory Class: II
Product Code: HJO
Dated: July 15, 2008
Received: July 17, 2008

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082031

Device Name:

Slit Lamp AIA – 11 Series: {Slit Lamp AIA – 11
Slit Lamp AIA – 11 3S
Slit Lamp AIA – 11 5S
Slit Lamp AIA – 11 ZOOM}

Slit Lamp AIA – 12 Series: {Slit Lamp AIA – 12
Slit Lamp AIA – 12 3S
Slit Lamp AIA – 12 5S
Slit Lamp AIA – 12 ZOOM}

Indications for Use:

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Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K082031